

SEARCH REQUEST FORM

Scientific and Technical Information Center

Requester's Full Name: Doersch Examiner #: 78084 Date: 6/26/03
 Art Unit: 3762 Phone Number: 605-1155 Serial Number: 091940253
 Mail Box and Bldg/Room Location: 3A11 Results Format Preferred (circle): PAPER DISK E-MAIL
SPE Angie Sykes

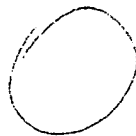
If more than one search is submitted, please prioritize searches in order of need.

Please provide a detailed statement of the search topic, and describe as specifically as possible the subject matter to be searched. Include the elected species or structures, keywords, synonyms, acronyms, and registry numbers, and combine with the concept or utility of the invention. Define any terms that may have a special meaning. Give examples or relevant citations, authors, etc, if known. Please attach a copy of the cover sheet, pertinent claims, and abstract.

Title of Invention: Duck-bill-shaped implantable cardiover-
defibrillator or anti-arrhythmia
 Inventors (please provide full names): Gust Bardy, Riccardo Cappato,
William Kissman, Gary Sanders
 Earliest Priority Filing Date: 9/18/00

For Sequence Searches Only Please include all pertinent information (parent, child, divisional, or issued patent numbers) along with the appropriate serial number.

Surgical implantation of implantable
 defibrillators where a single incision is
 made at the level of the cardiac apex or
 (heart)
 a single incision is made in the left anterior
 axillary line, where . . .



STAFF USE ONLY

STAFF USE ONLY	Type of Search	Vendors and cost where applicable
Searcher: <u>Juanne Horvath</u>	NA Sequence (#) _____	STN _____
Searcher Phone #: _____	AA Sequence (#) _____	Dialog _____
Searcher Location: _____	Structure (#) _____	Questel/Orbit _____
Date Searcher Picked Up: _____	Bibliographic _____	Dr.Link _____
Date Completed: _____	Litigation _____	Lexis/Nexis _____
Searcher Prep & Review Time: _____	Fulltext _____	Sequence Systems _____
Clerical Prep Time: _____	Patent Family _____	WWW/Internet _____
Online Time: _____	Other _____	Other (specify) _____



STIC Search Report

EIC 3700

STIC Database Tracking Number: 97595

TO: Kristen Droesch
Location: CP2 3A11
Art Unit: 3762

Case Serial Number: 09/940283

From: Jeanne Horrigan
Location: EIC 3700
CP2-2C08
Phone: 305-5934

jeanne.horrigan@uspto.gov

Search Notes

Attached are the search results for method of implanting a defibrillator, including results of prior art searches in foreign/international patent databases and in medical and general sci/tech non-patent literature databases. As you requested, the package does not include the results of the inventor search in the foreign/international patent databases. However, it does include references to two articles by the inventors prior to the priority filing date that I thought might be useful. I also searched the Web using the Scirus search engine.

The results are organized into four sets: inventor, non-patent literature, and foreign and international patents.

Results appear after the database names and search strategy used for those results. I tagged only one item that I thought seemed most relevant, but I **suggest that you review all of the results (especially because I had a hard time understanding the art).**

Also attached is a search feedback form. Completion of the form is voluntary. Your completing this form would help us improve our search services.

I hope the attached information is useful. Please feel free to contact me (phone 305-5934 or email jeanne.horrigan@uspto.gov) if you have any questions or need additional searching on this application.



File 155:MEDLINE(R) 1966-2003/Jun W4
File 5:Biosis Previews(R) 1969-2003/Jun W4
File 73:EMBASE 1974-2003/Jun W4
File 34:SciSearch(R) Cited Ref Sci 1990-2003/Jun W4
File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec

Set	Items	Description
S1	628	AU='BARDY G H' OR AU='BARDY G.H.' OR AU='BARDY G' OR AU='B- ARDY G.' OR AU='BARDY GH' OR AU='BARDY GUST' OR AU='BARDY GUST H'
S2	396	AU='CAPPATO R' OR AU='CAPPATO R.' OR AU='CAPPATO RICARDO' - OR AU='CAPPATO RICCARDO'
S3	5	AU='RISSMANN W' OR AU='RISSMANN W J' OR AU='RISSMANN W.' OR AU='RISSMANN W.J.' OR AU='RISSMANN WJ'
S4	10	AU='SANDERS G H'
S5	1	AU='SANDERS G.H.'
S6	45	AU='SANDERS GH'
S7	0	S1 AND S2 AND S3 AND S4:S6
S8	0	DEBRILLAT? AND INCISION? ?
S9	193	DEFIBRILLAT? AND INCISION?
S10	5	S1:S6 AND S9
S11	0	S10/2001:2003
S12	5	S10
S13	2	RD (unique items)

13/7/1 (Item 1 from file: 155)

DIALOG(R) File 155:MEDLINE(R)

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07878058 93338875 PMID: 8339416

**A simplified, single-lead unipolar transvenous cardioversion-
defibrillation system.**

Bardy G H ; Johnson G; Poole J E; Dolack G L; Kudenchuk P J; Kelso D;
Mitchell R; Mehra R; Hofer B

Department of Medicine, University of Washington, Seattle.

Circulation (UNITED STATES) Aug 1993, 88 (2) p543-7, ISSN 0009-7322

Journal Code: 0147763

Contract/Grant No.: R01-HL-48814-01; HL; NHLBI

Document type: Journal Article

Languages: ENGLISH

Main Citation Owner: NLM

Record type: Completed

BACKGROUND. Transvenous implantable cardioverter- **defibrillators** provide significant advantages in the treatment of patients with life-threatening ventricular arrhythmias. However, present technology requires considerable electrophysiology expertise, multiple **incisions**, and long operative times for successful implementation. METHODS AND RESULTS. In this study, we present a prototype of a new, easy-to-insert unipolar transvenous **defibrillation** system that has the reliability of epicardial **defibrillation** but the ease of pacemaker insertion. This system incorporates a single anodal right ventricular **defibrillation** electrode using a 65% tilt biphasic pulse delivered to a 108-cm² surface area pulse generator titanium alloy shell as an active cathode placed in a left infraclavicular pocket. Testing of this system was performed before implantation of a standard nonthoracotomy-transvenous **defibrillation** system in 40 consecutive patients with a history of ventricular tachycardia or fibrillation. The simplified unipolar single-lead system resulted in a **defibrillation** threshold of 9.3 +/- 6.0 J with 37 of 40 patients (93%)

having a **defibrillation** threshold of less than 20 J. Moreover, the unipolar **defibrillation** system was efficiently used requiring only 3.4 +/- 0.8 ventricular fibrillation inductions to measure the **defibrillation** threshold and 100 +/- 28 minutes to implement. CONCLUSIONS. This new unipolar transvenous **defibrillation** system is as simple to insert as a pacemaker, requires few ventricular fibrillation inductions, demands less technical expertise, and provides **defibrillation** at energy levels comparable to that reported with epicardial lead systems. It should substantially reduce the morbidity, time, and cost of **defibrillator** implantation.

Record Date Created: 19930902
Record Date Completed: 19930902

13/7/2 (Item 1 from file: 5)
DIALOG(R) File 5: Biosis Previews(R)
(c) 2003 BIOSIS. All rts. reserv.

08544394 BIOSIS NO.: 199344094394

Simplicity and efficacy of a single incision pectoral implant unipolar defibrillation system.

AUTHOR: **Bardy Gust H** ; Johnson George; Poole Jeanne E; Dolack G Lee; Kudenchuk Peter J; Hofer Bradley; Mehra Rahul; Mitchell Robin; Kelso David
AUTHOR ADDRESS: Univ. Washington, Seattle, WA**USA
JOURNAL: Journal of the American College of Cardiology 21 (2 SUPPL. A):p 66A 1993

CONFERENCE/MEETING: 42nd Annual Scientific Session of the American College of Cardiology Anaheim, California, USA March 14-18, 1993

ISSN: 0735-1097

RECORD TYPE: Citation

LANGUAGE: English

File 155:MEDLINE(R) 1966-2003/Jun W4
File 5:Biosis Previews(R) 1969-2003/Jun W4
File 73:EMBASE 1974-2003/Jun W4
File 34:SciSearch(R) Cited Ref Sci 1990-2003/Jun W4
File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec
File 144:Pascal 1973-2003/Jun W2
File 6:NTIS 1964-2003/Jun W5
File 8:Ei Compendex(R) 1970-2003/Jun W3
File 2:INSPEC 1969-2003/Jun W3
File 99:Wilson Appl. Sci & Tech Abs 1983-2003/May
File 65:Inside Conferences 1993-2003/Jun W4
File 94:JICST-EPlus 1985-2003/Jun W4
File 35:Dissertation Abs Online 1861-2003/May
File 95:TEME-Technology & Management 1989-2003/Jun W2

Set	Items	Description
S1	30280	DEFIBRILLATOR?
S2	1518048	IMPLANT? OR GRAFT?
S3	110199	INCISION? ?
S4	126223	APEX OR AXILLARY OR AXILLA OR ARMPIT OR ARM()PIT
S5	1083	INFRAMAMMARY OR (UNDER OR UNDERNEATH OR BENEATH OR BELOW) (-2W) (BREAST OR MAMMARY() GLAND? ?)
S6	378851	SUBCUTANEOUS?
S7	31403	RIBCAGE OR RIB()CAGE OR RIBS
S8	22251	S1(S)S2
S9	703	S3(10N)S4
S10	11	S8 AND S9
S11	0	S5 AND S10
S12	8	S6 AND S10
S13	0	S7 AND S12
S14	0	S12/2001:2003
S15	8	S12
S16	2	RD (unique items)
S17	3	S8 AND S5
S18	3	S17 NOT S12
S19	1	RD (unique items)
S20	64260	RIB OR RIBS
S21	11381056	BETWEEN
S22	0	S S21(5W)S20
S23	2162	S21(5W)S20
S24	4	S8 AND S23
S25	4	S24 NOT (S12 OR S17)
S26	1	RD (unique items)

16/7/1 (Item 1 from file: 155)

DIALOG(R)File 155:MEDLINE(R)

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08553013 95241313 PMID: 7724391

Subpectoral implantation of ICD generators: long-term follow-up.

Thakur R K; Ip J H; Mehta D; Jung J Y; Collar A; Camunas J; Gomes J A
Arrhythmia Service, Thoracic and Cardiovascular Institute, Lansing, MI
48910.

Pacing and clinical electrophysiology - PACE (UNITED STATES) (Jan 1995,)
18 (1 Pt 2) p159-62, ISSN 0147-8389 Journal Code: 7803944

Document type: Journal Article

Languages: ENGLISH

Main Citation Owner: NLM

ASRC Searcher: Jeanne Horrigan
Serial 09/940283
June 27, 2003

Record type: Completed

A nonthoracotomy surgical approach using an endocardial electrode and combined **implantation** of a **subcutaneous** patch and the **implantable** cardioverter **defibrillator** (ICD) generator in a subpectoral pocket has been described. We report the long-term follow-up results in patients undergoing **implantation** using this approach. The patient population consisted of 28 patients (22 men and 6 women) with a mean age of 59 +/- 12 years. The underlying heart disease consisted of coronary artery disease in 20 patients and dilated cardiomyopathy in 8 patients. Sustained ventricular tachycardia was the mode of presentation in 16 patients and sudden cardiac death in 12 patients. The mean left ventricular ejection fraction was 31% +/- 6%. The lead system consisted of an 8 French bipolar passive fixation rate sensing lead positioned at the right ventricular **apex**, an 11 French spring coil electrode positioned at the superior vena cava-right atrial junction (surface area 700 mm²), and submuscular placement of a large patch (surface area 28 cm²) on the anterolateral chest wall near the cardiac **apex** via a **submammary** incision. A defibrillation threshold of < or = 15 joules (J) was required for **implantation**. This criterion was not satisfied in five patients; thus, a limited thoracotomy was performed via the submammary incision, and the large patch was placed epicardially. The mean R wave amplitude was 12 +/- 3 mV, the mean pacing threshold was 1.0 +/- 0.5 V at 0.5 msec, and the mean defibrillation threshold was 12.6 +/- 3 J. ICD generators **implanted** were the Ventak-P in 17, PCD-7217 in 5, and the Cadence V-100 in 6 patients. (ABSTRACT TRUNCATED AT 250 WORDS)

Record Date Created: 19950519

Record Date Completed: 19950519

16/7/2 (Item 2 from file: 155)

DIALOG(R) File 155:MEDLINE(R)

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08382530 95070506 PMID: 7979724

Single-incision implantation of cardioverter defibrillators using nonthoracotomy lead systems.

Hammel D; Block M; Geiger A; Bocker D; Stadlbauer T; Breithardt G; Scheld H H

Department of Cardiovascular Surgery, Hospital of the Westphalian Wilhelms University of Muenster, Germany.

Annals of thoracic surgery (UNITED STATES) Dec 1994, 58 (6) p1614-6, ISSN 0003-4975 Journal Code: 15030100R

Comment in Ann Thorac Surg. 1994 Dec;58(6) 1572; Comment in PMID 7979717

Document type: Journal Article

Languages: ENGLISH

Main Citation Owner: NLM

Record type: Completed

This study describes the placement of a newly designed **implantable** cardioverter **defibrillator** in a subpectoral device pocket using the incision for venous access in 16 patients undergoing **implantation** of an **implantable** cardioverter **defibrillator** with a nonthoracotomy lead system. The endocardial lead system consisted of a right atrial/superior vena cava defibrillation spring electrode and a right ventricular bipolar sensing/defibrillation electrode, inserted by cephalic venotomy or by puncturing of the subclavian vein. As a result of intraoperative testing using biphasic shocks the defibrillation threshold (DFT) had to be less than 24 J, otherwise an additional **subcutaneous** patch electrode was placed in the lateral chest wall near the cardiac **apex** through another **incision**. All patients received a nonthoracotomy lead system in

combination with a subpectoral device placement. In 11 of 16 patients the endocardial leads alone were sufficient (DFT, 13.4 +/- 7.0 J), 5 of 16 patients (31%) required an additional **subcutaneous** patch electrode to achieve proper device function (DFT, 14.6 +/- 9.0 J). The operation lasted 93 +/- 20 minutes. This was a significant ($p < 0.05$) lower time consumption than standard nonthoracotomy approach combined with abdominal device placement (120 +/- 50 minutes). There were no postoperative complications. During follow-up period (average, 4 months), none of the patients reported major local symptoms, especially no device migration occurred. This approach, in contrast to an abdominal device placement, avoids another incision and **subcutaneous** tunneling of leads. In 11 of 16 patients **defibrillator** **implantation** by a single incision in the deltoideopectoral groove was possible.

Record Date Created: 19941228

Record Date Completed: 19941228

19/7/1 (Item 1 from file: 155)

DIALOG(R) File 155:MEDLINE(R)

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07233184 92095717 PMID: 1755693

Cosmetic approach for placement of the automatic implantable
cardioverter- defibrillator in young women.

Curiale S; Rosenfeld L E; Elefteriades J A

Section of Cardiothoracic Surgery, Yale University School of Medicine,
New Haven, CT 06510.

Annals of thoracic surgery (UNITED STATES) Dec 1991, 52 (6) p1340-1,
ISSN 0003-4975 Journal Code: 15030100R

Document type: Journal Article

Languages: ENGLISH

Main Citation Owner: NLM

Record type: Completed

A surgical approach is described for a more cosmetically acceptable placement of the automatic **implantable** cardioverter- **defibrillator** in young women. The transvenous sensing lead and the vena caval spring electrode are placed through a small subclavicular incision. The left ventricular patch electrode is placed through an anterior minithoracotomy in the crease **under** the left **breast**. A small transverse incision in the left lower quadrant is used to place the generator under the external oblique fascia in the low abdominal wall. Minimal cosmetic impairment from incisions and hardware results.

Record Date Created: 19920127

Record Date Completed: 19920127

26/6/1 (Item 1 from file: 155)

08699963 95388568 PMID: 7659570

**Subclavian crush syndrome complicating transvenous cardioverter
defibrillator systems.**

May 1995

File 155:MEDLINE(R) 1966-2003/Jun W4

Set	Items	Description
S1	3427	'DEFIBRILLATORS, IMPLANTABLE' OR DC='E7.296.319.175.' OR D-C='E7.695.175.' OR 'CARDIOVERTER-DEFIBRILLATORS, IMPLANTABLE' OR 'IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS' OR 'IMPLANTABLE - DEFIBRILLATORS'
S2	5832	DEFIBRILLATOR?
S3	301566	IMPLANT? OR GRAFT?
S4	21162	INCISION? ?
S5	25485	APEX OR AXILLARY OR AXILLA OR ARMPIT OR ARM()PIT
S6	324	INFRAMAMMARY OR (UNDER OR UNDERNEATH OR BENEATH OR BELOW) (-2W) (BREAST OR MAMMARY()GLAND? ?)
S7	76793	SUBCUTANEOUS?
S8	8958	RIBCAGE OR RIB()CAGE OR RIBS
S9	0	S1(L)SU
S10	16	S1 AND S3(10N)S4
S11	109	S7 AND S8
S12	0	S10 AND S11
S13	4	S1 AND S4(10N)S5
S14	0	S1 AND S6
S15	0	S1 AND S7(5N)S8

13/7/1

DIALOG(R) File 155:MEDLINE(R)

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11906180 99349364 PMID: 10420879

Canine model of ventricular fibrillation using programmed stimuli and localized myocardial warming or cooling.

Tachibana H; Kubota I; Yamaki M; Watanabe T; Tomoike H

First Department of Internal Medicine, Yamagata University School of Medicine, Japan.

Japanese heart journal (JAPAN) Mar 1999, 40 (2) p179-88, ISSN 0021-4868 Journal Code: 0401175

Document type: Journal Article

Languages: ENGLISH

Main Citation Owner: NLM

Record type: Completed

The purpose of this study was to establish an animal model in which ventricular fibrillation (VF) can be induced reproducibly and defibrillation can be accomplished repeatedly. The left anterior descending artery (LAD) was cannulated and perfused with blood from the carotid artery in eleven open-chest dogs. Electrodes of the internal defibrillator were inserted in the cavities of the left atrium and left ventricle via **incisions** in the left atrial appendage and left ventricular **apex**. The perfused blood temperature was modulated to produce regional myocardial warming (42 degrees C) or cooling (28 degrees C). In all dogs, VF was repeatedly induced by the combination of warming and left ventricular extrastimuli and by the combination of cooling and right ventricular extrastimuli. The VF was quickly defibrillated by use of the internal defibrillator. The mechanism of VF was found to be reentry by the analysis of activation sequences. This VF model may be useful when evaluating the efficacy of antiarrhythmic drugs because of the high reproducibility.

Record Date Created: 19990805

Record Date Completed: 19990805

13/7/4

DIALOG(R) File 155:MEDLINE(R)

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07930238 93391071 PMID: 7690941

Effective defibrillation in pigs using interleaved and common phase sequential biphasic shocks..

Guse P A; Rollins D L; Krassowska W; Wolf P D; Smith W M; Ideker R E

Department of Medicine, Duke University Medical Center, Durham, NC 27710.

Pacing and clinical electrophysiology - PACE (UNITED STATES) Aug 1993,

16 (8) p1719-34, ISSN 0147-8389 Journal Code: 7803944

Contract/Grant No.: HL-28429; HL; NHLBI; HL-42760; HL; NHLBI; HL-44066;

HL; NHLBI; +

Document type: Journal Article

Languages: ENGLISH

Main Citation Owner: NLM

Record type: Completed

Previous studies have shown that low internal defibrillation thresholds (DFTs) can be attained by using two pairs of electrodes and combining biphasic shocks with sequential timing. The purpose of this two-part study was to test the defibrillation efficacy of two new shock sequences, an interleaved biphasic, and a common phase sequential biphasic, that utilized two pairs of electrodes and were developed from the concept of sequential biphasic shocks. In the first part, defibrillation catheters were placed in the right ventricle and the superior vena cava of six anesthetized pigs. A small patch electrode was placed on the LV apex through a subxiphoid incision and a cutaneous patch was placed on the left thorax. The mean DFT energies for the interleaved biphasic (5.2 +/- 0.4 J) and the common phase sequential biphasic waveforms (5.4 +/- 0.4 J) were substantially less ($P < 0.0001$) than those for either the sequential monophasic (10.6 +/- 1.0 J) or single biphasic waveforms (9.0 +/- 1.0 J). In the second study, which used nine anesthetized pigs, the importance of phase reversal was demonstrated by the finding that the DFT energy of a common phase sequential biphasic shock (6.2 +/- 0.4 J) was much less than a common phase sequential monophasic shock (17.9 +/- 1.3 J, $P < 0.0001$); furthermore, the average DFT for four common phase sequential biphasic configurations (5.7 +/- 0.2 J) was much less than for a configuration that was similar except that current flow was not reversed in one phase so that no biphasic effect was present (19.7 +/- 1.2 J). The efficacy of common phase sequential biphasics was comparable to that of sequential biphasics. The effectiveness of sequential biphasics, interleaved biphasics, and common phase sequential biphasics is possibly due to two mechanisms: (A) an increase in the potential gradient during a later phase in regions that were low during the first phase, and (B) the exposure of most of the myocardium to a biphasic shock that reduces the minimum extracellular potential gradient needed to defibrillate.

Record Date Created: 19931021

Record Date Completed: 19931021

File 98:General Sci Abs/Full-Text 1984-2003/May
File 9:Business & Industry(R) Jul/1994-2003/Jun 26
File 16:Gale Group PROMT(R) 1990-2003/Jun 26
File 160:Gale Group PROMT(R) 1972-1989
File 148:Gale Group Trade & Industry DB 1976-2003/Jun 25
File 149:TGG Health&Wellness DB(SM) 1976-2003/Jun W3
File 636:Gale Group Newsletter DB(TM) 1987-2003/Jun 24
File 441:ESPICOM Pharm&Med DEVICE NEWS 2003/Jun W4
File 20:Dialog Global Reporter 1997-2003/Jun 27
File 442:AMA Journals 1982-2003/Dec B2
File 444:New England Journal of Med. 1985-2003/Jun W5

Set	Items	Description
S1	14815	DEFIBRILLATOR?
S2	222634	IMPLANT? OR GRAFT?
S3	22876	INCISION? ?
S4	66778	APEX OR AXILLARY OR AXILLA OR ARMPIT OR ARM()PIT
S5	645	INFRAMAMMARY OR (UNDER OR UNDERNEATH OR BENEATH OR BELOW) (- 2W) (BREAST OR MAMMARY()GLAND? ?)
S6	31300	SUBCUTANEOUS?
S7	35539	RIBCAGE OR RIB()CAGE OR RIBS
S8	5535	S1(5N)S2
S9	284	S3(10N)S4
S10	5	S6(5N)S7
S11	1	S8(S)S9
S12	0	S8(S)S5
S13	0	S8A ND S5
S14	4	S8 AND S5
S15	4	S14 NOT S11
S16	2	RD (unique items)
S17	0	S8(S)S6(5N)S7
S18	1170	BETWEEN(5W) (RIB OR RIBS)
S19	0	S8(S)S18
S20	3	S8 AND S18
S21	0	S8 AND S6(5N)S7

11/3,AB/1 (Item 1 from file: 160)

DIALOG(R)File 160:Gale Group PROMT(R)
(c) 1999 The Gale Group. All rts. reserv.
00651318

An automatic implantable defibrillator can now be inserted in the chest without surgery, by running 1 of the defibrillator's 2 electrodes into the right atrium via the internal jugular vein, and placing the other over the left ventricle's apex through an incision at the xiphoid and an opening into the pericardium, according to researchers at Johns Hopkins.

Medical World News June 8, 1981 p. 73

The power unit is inserted through a minor abdominal incision and placed under the skin as in the original procedure. The implantation method has significantly reduced hospital stays from 2-3 wks to 1 wk. The automatic defibrillator can correct potentially lethal arrhythmia.

16/3,AB,K/2 (Item 1 from file: 149)

DIALOG(R)File 149:TGG Health&Wellness DB(SM)
(c) 2003 The Gale Group. All rts. reserv.
01412542 SUPPLIER NUMBER: 13441775 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Thoracoscopic implantation of the implantable cardioverter
defibrillator . (Minimally Invasive Techniques)

File 350:Derwent WPIX 1963-2003/UD,UM &UP=200340

File 347:JAPIO Oct 1976-2003/Feb(Updated 030603)

File 371:French Patents 1961-2002/BOPI 200209

Set	Items	Description
S1	2003	DEFIBRILLATOR?
S2	180843	IMPLANT? OR GRAFT?
S3	10292	INCISION? ?
S4	28374	APEX OR AXILLARY OR AXILLA OR ARMPIT OR ARM()PIT
S5	68	INFRAMAMMARY OR (UNDER OR UNDERNEATH OR BENEATH OR BELOW) (- 2W) (BREAST OR MAMMARY() GLAND? ?)
S6	18582	SUBCUTANEOUS?
S7	76361	RIBCAGE OR RIB()CAGE OR RIBS
S8	1307	IC=A61N-001/39
S9	895	S1(5N)S2
S10	52	S3(10N)S4
S11	0	S8:S9 AND S10
S12	0	S1 AND S2 AND S10
S13	1	(S1:S2 OR S8) AND S5
S14	2	S1 AND S2 AND S6(S)S7
S15	3	S13:S14 [duplicates]
S16	16302	BETWEEN(6N) (RIB OR RIBS)
S17	4	S1 AND S2 AND S16
S18	3	S17 NOT S15
S19	1	(S8 AND S6(S)S7) NOT S14
S20	0	(S8 AND S16) NOT (S15 OR S17)

18/7/3 (Item 3 from file: 350)

DIALOG(R)File 350:Derwent WPIX

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010363365

WPI Acc No: 1995-264678/199535

Defibrillator **electrode for implantation - has a flexible conductive mesh and insulator for insertion through a small opening in a simple surgical procedure**

Patent Assignee: FOGARTY T J (FOGA-I)

Inventor: FOGARTY T J; HOWELL T A

Number of Countries: 019 Number of Patents: 005

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
EP 665030	A2	19950802	EP 95630004	A	19950126	199535 B
CA 2117618	A	19950729	CA 2117618	A	19940901	199542
US 5464447	A	19951107	US 94188573	A	19940128	199550
US 5618287	A	19970408	US 94188573	A	19940128	199720
			US 95406125	A	19950317	
US 5690648	A	19971125	US 94188573	A	19940128	199802
			US 95406372	A	19950317	
			US 96620986	A	19960322	

Priority Applications (No Type Date): US 94188573 A 19940128; US 95406125 A 19950317; US 95406372 A 19950317; US 96620986 A 19960322

Cited Patents: No-SR.Pub

Patent Details:-

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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EP 665030	A2	E	14	A61N-001/05	
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Designated States (Regional): AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE

US 5464447	A		12	A61N-001/05	
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CA 2117618 A A61N-001/05
Abstract (Basic): EP 665030 A

Dwg. 0/19

Dwg.16/19

A method of surgically implanting a defibrillator electrode within a patient comprises deflating the left lung of a patient; making an opening in the chest of the patient between a 2nd rib and a 6th rib of the patient; inserting a trocar into the opening between the 2nd rib and the 6th rib; inserting an optical device into the trocar to permit observation within the patient; making a subxiphoid opening; releasably securing one end of a defibrillator electrode to a first handle; releasably securing an opposite end of the defibrillator electrode to a second handle; rotating of the first and second handles toward each other to roll the defibrillator electrode; passing the first and second handles and the rolled defibrillator electrode through the subxiphoid opening to position the defibrillator electrode on a surface of the pericardium; rotating the first and second handles away from each other to unroll the defibrillator

electrode; and securing the **defibrillator** electrode to the pericardium.

Dwg.1/19

Derwent Class: A96; P34; S05

International Patent Class (Main): A61N-001/04; A61N-001/05

19/7/1 (Item 1 from file: 350)

DIALOG(R) File 350:Derwent WPIX

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008858850 **Image available**

WPI Acc No: 1991-362873/199150

Implantable tissue stimulating electrode assembly - includes side-by-side disposed electrode segments connected to common lead, with inter-segment spacing of at least 1.5 cm

Patent Assignee: CARDIAC PACEMAKERS INC (CARD-N); CARDIAC PACEMAKERS (CARD-N)

Inventor: DAHL R W; HAHN S J; HEIL J E; LANG D J; SWANSON D K

Number of Countries: 007 Number of Patents: 012

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
EP 460324	A	19911211	EP 90311986	A	19901101	199150 B
CA 2027744	A	19911207				199209
US 5203348	A	19930420	US 90533886	A	19900606	199317
US 5230337	A	19930727	US 90533886	A	19900606	199331
			US 92912950	A	19920714	
EP 460324	A3	19920708	EP 90311986	A	19901101	199334
US 5342407	A	19940830	US 90533886	A	19900606	199434
			US 92912924	A	19920713	
US 5360442	A	19941101	US 90533886	A	19900606	199443
			US 93967361	A	19930104	
EP 460324	B1	19960320	EP 90311986	A	19901101	199616
DE 69026081	E	19960425	DE 626081	A	19901101	199622
			EP 90311986	A	19901101	
US 5545202	A	19960813	US 90533886	A	19900606	199638
			US 93967361	A	19930104	
			US 94285802	A	19940804	
US 5603732	A	19970218	US 90533886	A	19900606	199713
			US 93967361	A	19930104	
			US 94285802	A	19940804	
			US 95554577	A	19951106	
CA 2027744	C	19990504	CA 2027744	A	19901016	199936

Priority Applications (No Type Date): US 90533886 A 19900606; US 92912950 A 19920714; US 92912924 A 19920713; US 93967361 A 19930104; US 94285802 A 19940804; US 95554577 A 19951106

Cited Patents: NoSR.Pub; EP 317490; AEP 347353; AFR 2200023; YUS 3333045; AUS 3654933; OY 1Jnl.Re; 00 EP0042; 90 WO0890

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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EP 460324	A		15		
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Designated States (Regional): DE FR GB IT NL

US 5203348	A		13	A61N-001/05	
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US 5230337	A		12	A61N-001/39	Div ex application US 90533886 Div ex patent US 5203348
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EP 460324	A3		15		
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US 5342407	A		12	A61N-001/39	Div ex application US 90533886 Div ex patent US 5203348
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an electrode including a plurality of compliant, electrically conductive electrode segments, each of said segments having a nominal width and a length exceeding the nominal width, said electrode segments

having respective and opposite first and second ends and being coupled to the distal end region of the lead for substantially simultaneous reception of tissue stimulating electrical pulses from a pulse generating means at the proximal end region of the lead, said electrode segments being arranged in spaced apart and side-by-side relation such that each of the electrode segments, over most of its length, is spaced apart from each one of the other electrode segments by a distance of at least 1.5 cm, each of the electrode segments being free of electrically insulative material at and along its periphery substantially over its entire length to provide an exposed reactive surface over substantially the entire length and periphery of the electrode segment, said electrode segments when receiving the tissue stimulating pulses cooperating to define an effective electrode area incorporating all of the electrode segments.

Dwg.1/24

US 5545202 A

A body implantable defibrillation system, including:

a defibrillation pulse generator;

a first defibrillation electrode implanted at least proximate the thoracic region, said first electrode including a plurality of compliant, electrically conductive electrode segments, each segment having a nominal width and a length exceeding the nominal width; a connecting means for electrically coupling the electrode segments for substantially simultaneous reception of defibrillation pulses from the defibrillation pulse generator; said electrode segments being arranged in spaced apart and side-by-side relation such that each of the electrode segments, over most of its length, is spaced apart from each of the other electrode segments by a distance of at least 1.5 cm; each of the electrode segments being free of electrically insulative material at and along its periphery over the entire length and periphery of the electrode segment; said electrode segments when receiving the defibrillation pulses cooperating to define an effective electrode area incorporating all of the electrode segments; a first coupling means electrically coupling the first defibrillation electrode and the defibrillation pulse generator;

a second defibrillation electrode implanted at least proximate the thoracic region and spaced apart from the first defibrillation electrode; and

a second coupling means electrically coupling the defibrillation pulse generator and the second electrode.

Dwg.1/24

US 5360442 A

Implantable electrodes for defibrillation are formed of number of electrode segments. Each of the segments is relatively long and narrow. The electrode segments can be parallel and spaced apart from one another a distance at least ten times the nominal width, with one end of each segment mounted to a transverse distal portion of an electrically conductive lead coupling the electrode to a defibrillation pulse generator. Alternatively, segments can branch or radiate outwardly from a common junction. Electrode segments may be portions of a single conductive path at the distal end of a lead from a pulse generator, arranged in either a spiral configuration or a serpentine configuration which can align electrode segments side by side, parallel and spaced apart.

The electrode segments can be formed of composite conductors in the form of titanium ribbons or wires with a sputtered outer layer of

platinum, or a silver core in a stainless steel tube with a platinum layer formed onto the tube.

USE/ADVANTAGE - Electrodes are highly compliant yet can provide large effective areas for defibrillation, enabling transthoracic pulsing arrangement of two electrodes on opposite sides of heart, implanted subcutaneously outside of thoracic region.

Dwg.11/24

US 5342407 A

Implantable electrodes for defibrillation are formed of electrode segments. Each of the segments is relatively long and narrow. The electrode segments can be parallel and spaced apart from one another a distance at least ten times the nominal width, with one end of each segment mounted to a transverse distal portion of an electrically conductive lead coupling the electrode to a defibrillation pulse generator.

Alternatively, segments can branch or radiate outwardly from a common junction. In yet another arrangement, electrode segments are portions of a single conductive path at the distal end of a lead from a pulse generator, arranged in either a spiral configuration or a serpentine configuration which can align electrode segments side by side, parallel and spaced apart.

ADVANTAGE - Electrodes are highly compliant yet can provide large effective areas for defibrillation, enabling transthoracic pulsing arrangement of two electrodes on opposite sides of heart, implanted subcutaneously outside of thoracic region.

Dwg.14/24

US 5230337 A

The process for applying defibrillation pulses to a human heart, involves implanting a first compliant electrode in a patient, subcutaneously, proximate the pleural cavity and outside of the **rib cage**, and on a first side of a thoracic region. A second compliant electrode **subcutaneously** is implanted proximate the pleural cavity and outside of the **rib cage** and on a second side of the thoracic region opposite the first side with at least a portion of the heart between the first electrode and the second electrode.

A defibrillation pulse generator is implanted and the first and second electrodes are electrically coupled to a defibrillation pulse generator. Defibrillation pulses are provided from the pulse generator, to the first electrode and from the first electrode to the second electrode via body tissue.

ADVANTAGE - Provides an implantable defibrillation electrode with a large effective surface area to lower the impedance at or near the electrode, without causing undue patient discomfort. Is easier to implant and readily conforms to the contours of its implant location

Dwg.22/24

US 5203348 A

The body implantable tissue stimulating electrode assembly, included: an elongate, electrically conductive lead (26) having a proximal and a distal ends. An electrode (16) comprises a number of compliant, conductive electrode segments (18,20,22) each having a nominal width of at most five millimetres and a length exceeding the nominal width. Each segment has respective and opposite first and second ends and is coupled to the distal end of the lead for simultaneous reception of tissue stimulating electrical pulses from a pulse generator at the proximal end of the lead.

The segments are arranged in spaced apart and side-by-side relation

such that each, over most of its length, is spaced from another segment by a distance of at least 1.5 cm. Each electrode segment is free of electrically insulative material at and along its periphery over its entire length to provide an exposed reactive surface, includes at least one electrically conductive cable having a highly conductive metal core within in a conductive metal tube. The segments when receiving the tissue stimulating pulses cooperate to define an effective electrode area incorporating all segments.

ADVANTAGE - Has large effective surface area to lower impedance at or near electrode without undue patient discomfort. Reduces non-uniform field distribution.

Dwg.1/24

Derwent Class: P34; S05

International Patent Class (Main): A61N-001/05; **A61N-001/39**

File 348:EUROPEAN PATENTS 1978-2003/Jun W04

File 349:PCT FULLTEXT 1979-2002/UB=20030626,UT=20030619

Set	Items	Description
S1	2474	DEFIBRILLATOR?
S2	113005	IMPLANT? OR GRAFT?
S3	17436	INCISION? ?
S4	22998	APEX OR AXILLARY OR AXILLA OR ARMPIT OR ARM()PIT
S5	290	INFRAMAMMARY OR (UNDER OR UNDERNEATH OR BENEATH OR BELOW) (- 2W) (BREAST OR MAMMARY()GLAND? ?)
S6	56226	SUBCUTANEOUS?
S7	39822	RIBCAGE OR RIB()CAGE OR RIBS
S8	0	A61N-001/39
S9	717	IC=A61N-001/39
S10	2089	S1(S)S2 OR S9
S11	26	S10 AND S3(10N)S4
S12	24	S10 AND S5
S13	32	S10 AND S6(6N)S7
S14	5	S1(S)S2(S)S3(10N)S4
S15	19	S1(S)S2(S)(S5 OR S6(6N)S7)
S16	16	S15 NOT S14
S17	9008	BETWEEN(6W) (RIB OR RIBS)
S18	24	S1(S)S2(S)S17
S19	19	S9 AND S18
S20	7	S19 NOT (S14 OR S15)

14/6/2 (Item 2 from file: 349)

00988430 **Image available**

CARDIOVERTER-DEFIBRILLATOR HAVING A FOCUSED SHOCKING AREA AND ORIENTATION
THEREOF

16/6/1 (Item 1 from file: 348)

00691996

WAVEFORM DISCRIMINATOR FOR CARDIAC STIMULATION DEVICES

16/6/2 (Item 2 from file: 348)

00589180

Subcostal patch electrode

16/6/3 (Item 1 from file: 349)

01009933 **Image available**

FLEXIBLE SUBCUTANEOUS IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR

16/6/4 (Item 2 from file: 349)

01009921 **Image available**

SUBCUTANEOUS ELECTRODE WITH IMPROVED CONTACT SHAPE FOR TRANSTHORASIC
CONDUCTION

16/6/5 (Item 3 from file: 349)

01009916 **Image available**

SUBCUTANEOUS IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR EMPLOYING A TELESOPING
LEAD

16/6/8 (Item 6 from file: 349)

00988432 **Image available**

POWER SUPPLY FOR A SUBCUTANEOUSLY IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR

16/6/11 (Item 9 from file: 349)
00988424 **Image available**
INSULATED SHELL FOR SUBCUTANEOUSLY IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR
CANISTER

16/6/13 (Item 11 from file: 349)
00988417 **Image available**
SUBCUTANEOUS ELECTRODE WITH IMPROVED CONTACT SHAPE FOR TRANSTHORACIC
CONDUCTION

16/6/15 (Item 13 from file: 349)
00556698 **Image available**
IMPLANTABLE STIMULATION LEAD FOR USE WITH AN ICD DEVICE HAVING AUTOCAPTURE
PACING FEATURES

16/6/16 (Item 14 from file: 349)
00289578 **Image available**
WAVEFORM DISCRIMINATOR FOR CARDIAC STIMULATION DEVICES

20/6/1 (Item 1 from file: 349)
01009934 **Image available**
MONOPHASIC WAVEFORM FOR ANTI-BRADYCARDIA PACING FOR A SUBCUTANEOUS
IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR

20/6/2 (Item 2 from file: 349)
01009932 **Image available**
CURRENT WAVEFORMS FOR ANTI-TACHYCARDIA PACING FOR A SUBCUTANEOUS
IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR

20/6/3 (Item 3 from file: 349)
01009931 **Image available**
CURRENT WAVEFORMS FOR ANTI-BRADYCARDIA PACING FOR A SUBCUTANEOUS
IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR

20/6/4 (Item 4 from file: 349)
00988433 **Image available**
BIPHASIC WAVEFORM FOR ANTI-BRADYCARDIA PACING FOR A SUBCUTANEOUSLY
IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR

20/6/5 (Item 5 from file: 349)
00988428 **Image available**
BIPHASIC WAVEFORM FOR A SUBCUTANEOUSLY IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR

20/6/6 (Item 6 from file: 349)
00988427 **Image available**
CANISTER DESIGNS FOR IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS

20/6/7 (Item 7 from file: 349)
00988425 **Image available**
CURVED IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR CANISTER



STIC Search Results Feedback Form

EIC 3700

Questions about the scope or the results of the search? Contact *the EIC searcher* or contact:

John Sims, EIC 3700 Team Leader
308-4836, CP2-2C08

Voluntary Results Feedback Form

➤ I am an examiner in Workgroup: Example: 3730

➤ Relevant prior art **found**, search results used as follows:

- ☐ 102 rejection
- ☐ 103 rejection
- ☐ Cited as being of interest.
- ☐ Helped examiner better understand the invention.
- ☐ Helped examiner better understand the state of the art in their technology.

Types of relevant prior art found:

- ☐ Foreign Patent(s)
- ☐ Non-Patent Literature
(journal articles, conference proceedings, new product announcements etc.)

➤ Relevant prior art **not found**:

- ☐ Results verified the lack of relevant prior art (helped determine patentability).
- ☐ Results were not useful in determining patentability or understanding the invention.

Comments:

Drop off or send completed forms to STIC/EIC3700 CP2 2C08



ASRC Searcher: Jeanne Horrigan
Serial 09/940283
June 27, 2003

Biotech (microfilm)
RC 705.D5
V.103 (1993)

Ely, Stephen W.; Kron, Irving L.
Chest, v103, n1, p271(2)
Jan, 1993

PUBLICATION FORMAT: Magazine/Journal ISSN: 0012-3692 LANGUAGE: English
RECORD TYPE: Fulltext TARGET AUDIENCE: Professional
WORD COUNT: 766 LINE COUNT: 00082
TEXT:

The **implantable** cardioverter **defibrillator** (ICD) has become accepted treatment for the management of certain malignant ventricular arrhythmias.[1-3...

... observation of the subsequent placement of two 5-mm trocars in the line of the **inframammary** anterolateral thoracotomy incision, as shown in Figure 1. A grasper and a pair of disposable...

...single stitch to hold the patches in place.

The procedure is completed by placing the **implantable** battery pack/**defibrillator** unit in a subcutaneous pouch in the subcostal position and by tunneling the four leads...

...unsatisfactory, the standard anterolateral thoracotomy can be performed, encompassing the two trocar incisions along the **inframammary** line.

The thoracoscopic approach for ICD placement produced minimal postoperative pain, and the patient had...

...ICD.

REFERENCES

[1] Mirowski M, Mower MM, Reid PR, Watkins L, Langer A. The automatic **implantable defibrillator**: new modality for the treatment of life-threatening ventricular arrhythmias. PACE 1982; 5:384-401...

453790

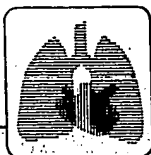
Kristen Droesch

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703-605-1185

COMPLETED

JUL - 1 2003



minimally invasive techniques

Thoracoscopic Implantation of the Implantable Cardioverter Defibrillator*

Stephen W. Ely, Ph.D., M.D.; and Irving L. Kron, M.D., F.C.C.P.

(*Chest* 1993; 103:271-72)

The implantable cardioverter defibrillator (ICD) has become accepted treatment for the management of certain malignant ventricular arrhythmias.¹⁻³ Implantation of the ICD usually requires an anterolateral thoracotomy through which the patch electrodes and sensing electrodes are placed, in either an intra- or an extrapericardial position, although subcostal and subxiphoid approaches are also used. This communication describes how a video-linked thoracoscopic system can be employed to implant an ICD.

ANESTHESIA AND PATIENT POSITION

General anesthesia is administered with a double-lumen endotracheal tube. The patient is positioned on the operating table in the supine position with a roll under the left side of the chest.

TROCAR PLACEMENT AND TECHNIQUE OF ICD IMPLANTATION

Three trocars are placed in the anterior chest wall as shown in Figure 1. The left lung is collapsed, and the chest is first entered using a knife and a Kelly clamp in a manner similar to that used for thoracostomy tube placement, at a site that would subsequently be used for thoracostomy tube drainage. This approach is used to avoid the theoretical possibility of injury to the underlying lung or heart with the disposable trocars. A 12-mm trocar (U.S. Surgical, Norwalk, Conn) is then placed, and a 10-mm forward-viewing thoracoscope attached to a chip camera and external video monitor is inserted. This gives an excellent view of the pleural cavity and aids in the internal observation of the subsequent placement of two 5-mm trocars in the line of the inframammary anterolateral thoracotomy incision, as shown in Figure 1. A grasper and a pair of disposable scissors (U.S. Surgical) are placed through these working channels. Under thoracoscopic guidance the pericardium is grasped and incised with the disposable scissors in a superior-inferior direction to expose the left ventricular apex and anterolateral wall.

The lateral trocar is then removed, and the incision is enlarged to allow the passage of the epicardial electrode placement device and the patch electrodes through the intercostal space without rib retraction. The patch electrodes are placed intrapericardially, first posteriorly and then anteriorly, followed by placement of the sensing electrodes in an area of left ventricular myocardium devoid of epicardial vessels. The pericardium is then approximated with a single stitch to hold the patches in place.

The procedure is completed by placing the implantable battery pack/defibrillator unit in a subcutaneous pouch in the subcostal position and by tunneling the four leads over the ribs using a DeBakey vascular tunneler. After appropriate testing of the device, a thoracostomy tube is placed through the site previously occupied by the thoracoscope, the lung is expanded, and the incision is closed in two layers.

PATIENT DATA

A 23-year-old man with no past medical history was referred to the University of Virginia after suffering an episode of near sudden death while hunting. He was successfully resuscitated with cardiopulmonary resuscitation and cardioversion. Cardiac catheterization revealed normal coronary anatomy without inducible vasospasm; an electrophysiologic study was normal, and programmed stimuli

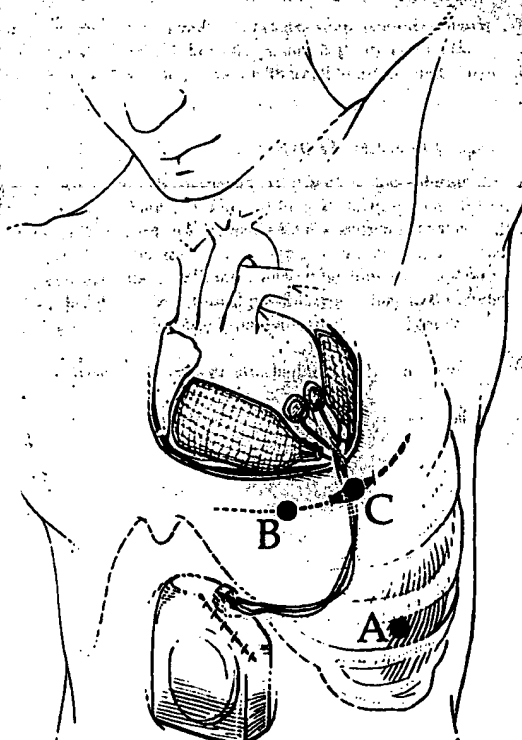


FIGURE 1. Position of trocar placement. A = 12-mm trocar for thoracoscope and subsequent thoracostomy tube. B = 5-mm trocar for placement of grasper. C = 5-mm trocar for placement of scissors and site of incision for placement of ICD patches and sensing electrodes.

*From the Department of Surgery, Division of Thoracic and Cardiovascular Surgery, University of Virginia Health Sciences Center, Charlottesville.

Reprint requests: Dr. Kron, University of Virginia Hospital, Box 310, Charlottesville 22908

tion failed to produce ventricular tachycardia. Because of the significant risk of recurrence of malignant arrhythmia, the patient was referred for ICD implantation which was performed using the described technique. The patient's recovery was rapid, uneventful, and with minimal postoperative pain.

COMMENT

Thoracoscopy is not a new modality, but it is finding new applications to problems in thoracic surgery.^{4,7} The use of this approach for ICD implantation gives excellent exposure and magnification of the operative field for viewing by the surgeon, assistant, scrub nurse, and cardiologists. Bleeding can be controlled by electrocautery. Rescue defibrillation can be accomplished with direct placement of pediatric defibrillator paddles through the ICD insertion site should the ICD patches or external 12 patches fail to provide defibrillation during testing of the device. If the thoroscopic approach should turn out to be unsatisfactory, the standard anterolateral thoracotomy can be performed, encompassing the two trocar incisions along the inframammary line.

The thoroscopic approach for ICD placement produced minimal postoperative pain, and the patient had an early return to normal activity. The avoidance of a painful thoracotomy incision should have a positive effect on the morbidity of this procedure, particularly in patients with borderline pulmonary function. How-

ever, further clinical experience will be required to accurately evaluate the short-term and long-term benefits and limitations of the thoroscopic implantation of the ICD.

REFERENCES

- 1 Mirowski M, Mower MM, Reid PR, Watkins L, Langer A. The automatic implantable defibrillator: new modality for the treatment of life-threatening ventricular arrhythmias. *PACE* 1982; 5:384-401
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- 7 Nathanson LK. Basic instrumentation and operative technique for laparoscopic surgery. In: Cuschieri A, ed. *Laparoscopic biliary surgery*. London: Blackwell Scientific, 1990; 33

LOCAL SYSTEM OF THE HEART

Table of Contents

- The Electrical System of the Heart:
 - Where is it, what does it do?
- What are Arrhythmias?
- You Need an Electrophysiologic Study (EP Study):
 - What is it?
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- Your Doctor Advised a Permanent Pacemaker:
 - What is a pacemaker
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- You have Atrial Fibrillation:
 - What do you need to know?
- You have Recurrent Fainting Spells:
 - What should you do?
 - What can your doctor do?

responding to medications; certain kinds of ventricular tachycardia.

What does the ablation procedure entail from the patient's perspective?

Actually, not much more than the regular EP study. In fact, in most circumstances the ablation will be part of your EP study. At our institution, when we are certain that a patient will undergo an ablation, we also have an anesthesiologist in attendance, so that the patient is asleep during the entire procedure. In one specific circumstance - RF ablation of the AV node - a permanent pacemaker is implanted after the ablation. In all other cases a pacemaker is not an anticipated result of the procedure, although in rare cases inadvertent damage to the AV node or His bundle has necessitated insertion of a permanent pacemaker prior to discharging the patient from the hospital. While other rare complications of the procedure have been reported, these complications are unlikely to occur in laboratories that have a great deal of experience with the procedure.

Is there any special follow-up after ablation?

No. Your doctor will want to repeat the ECG occasionally, but most centers no longer do repeat EP studies after a successful ablation. Some doctors prescribe aspirin for several months after the ablation, but definitive studies have not been done to demonstrate its efficacy. One of the best-liked aftermaths of a successful ablation is the ability of the patient to discontinue antiarrhythmic medications after the procedure.



YOUR DOCTOR HAS RECOMMENDED AN IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR (ICD or AICD): What's it all about (Alfie)?

What's an ICD and why do I need one?

This device is still another part of the "revolution" that has taken place over the past decade in the treatment of patients with cardiac arrhythmias. The device is an automatic detector of fast and potentially-lethal heart rhythms; the ICD can deliver several kinds of rapid and effective treatments designed to promptly terminate these rhythms. In essence, the automatic treatments consist of either rapidly pacing the heart (briefly) or delivering small internal electric shocks directly to the heart, or a sequential combination of both. At the time of implantation your doctor will determine which is the best treatment strategy for your arrhythmia. The device consists of the pulse

generator and its attached electrode leads, in a manner analogous to the permanent pacemaker described above.

Why you?

Because your doctor has determined (at EPS or by reviewing you medical records and history) that you have the potential for the recurrence of cardiac arrhythmias which can be fatal, the arrhythmias are called ventricular tachycardia or ventricular fibrillation. Almost certainly you have had at least one episode of such an arrhythmia, possibly causing an episode of loss of consciousness. Furthermore, your physician has decided that in your case the ICD is a better choice of treatment than long-term therapy with antiarrhythmic medications or ablation (see above) of your arrhythmia.

How is the ICD implanted?

In 1996, the surgery is very similar to the surgery performed for implantation of a permanent pacemaker. At our institution we ask the anesthesiologist to administer general anesthesia (in contrast to pacemaker surgery). We prefer to implant the pulse generator ("the can") behind the left pectoral (breast) muscle in your chest, so that the incision will be near your left arm-pit (axilla). Usually the patient can go home 1-2 days after the surgery.

What kind of follow-up is entailed by this device?

You will need to see your doctor every 2-3 months for an evaluation of the device's status. This is a painless procedure, as the doctor will place a wand over the can and "talk" to it electronically. Your doctor will then be able to ascertain whether or not you have had arrhythmia recurrences and how effective the device has been in treating these episodes. As well, your doctor will be able to assess the status of your battery, which will need replacement within 3-5 years of implantation (the entire pulse generator is replaced, but not the leads, so that this can be done as an outpatient).

Will I need any special medications after the surgery?

This is, of course, a very individual matter. You are likely to continue taking those medications that are not related specifically to arrhythmias. In many, but not all, rhythm medications can be stopped after the surgery. In some patients, medications need to be continued or started in order to minimize the frequency of ICD therapy, particularly if the therapy (i.e., shock) is perceived by the patient.

Will I be able to lead a normal life with the ICD?

Will I be able to drive?

In most cases your daily life should not be hampered by the ICD at all. After the requisite healing period, your physical activities should return to your pre-surgical level, although contact sports will be discouraged. Regarding driving, this is an individual decision made by your doctor. If your preoperative event was loss of consciousness, your doctor may choose to forbid you from driving a car for at least several months after surgery, in order to see your ability to function once you experience an arrhythmia and its termination by the ICD. Incidentally, you should have no trouble going through airport security metal detectors, since you will have a special ID card identifying you and your device. This will enable you to go around the metal detectors and avoid setting off their alarm.



ATRIAL FIBRILLATION:

A very common Arrhythmia

How common is atrial fibrillation?

The term describes a condition in which your atria are beating in a very rapid and disorganized fashion. Your lower chambers (ventricles) will respond to the atrial rhythm by beating in an irregular cadence, with rates ranging from quite slow to exceedingly fast. The arrhythmia most frequently seen by doctors (other than isolated "extra beats" such as the almost ubiquitous PVC's and PAC's) is atrial fibrillation. More than 200,000 new cases of atrial fibrillation are diagnosed in this country every year, and more than 1,000,000 patients have atrial fibrillation in the US.

What causes atrial fibrillation?

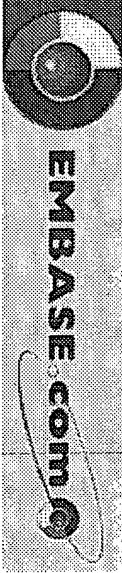
Doctors don't always know the cause, but certain conditions are associated with this arrhythmia. They include:

- Atherosclerotic heart disease
- Disease of the sinus node (your natural pacemaker)
- Disease of one or more of your heart valves
- During the recovery phase of open-heart surgery
- Lung disease
- Thyroid gland hyperactivity
- Acute heart attack

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Winter, J. / Heil, J.E. / Schumann, C. / Lin, Y. / Schannwell, C.M. / Michel, U. / Schipke, J.D. / Schulte, H.D. / Gams, E., *European Journal of Cardio-Thoracic Surgery*, Oct 1998

Objectives: The effect of implantable cardioverter/defibrillator (ICD) lead placement in the right ventricle (RV) on defibrillation efficacy has not been thoroughly investigated. Therefore, the goal of this combined experimental and...

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Cardall, T.Y. / Chan, T.C. / Brady, W.J. / Perry, J.C. / Vilke, G.M. / Rosen, P., *Journal of Emergency Medicine*, May 1999

Many people benefit from the implantation of cardiac pacemakers for management of certain cardiac dysrhythmias. These patients are seen regularly in the emergency department with a variety of pacemaker complications and malfunctions. The...

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Kuhlkamp, V. / Khalighi, K. / Dornberger, V. / Ziemer, G., *The Annals of Thoracic Surgery*, Oct 1997

Occasional patients have excessive defibrillation energy requirements despite appropriate transvenous defibrillation lead position and the use of biphasic shocks. A single-element subcutaneous array electrode was implanted in 2 patients...

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Kennergren, C., *The American Journal of Cardiology*^(R), Sep 1996

Implantable cardioverter-defibrillator (ICD) treatment has been in use since 1980 to prevent sudden cardiac death. The high efficacy of the original epicardial systems to terminate tachyarrhythmias was impaired by a substantial...

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This article presents a comparison of the costs and the cost-effectiveness of defibrillator implantation in a hypothetical scenario for the years 1996-2000, with recently reported actual data from the Dutch prospective study over the...

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- ☐ 6. Multicenter Experience With a Pectoral Unipolar Implantable Cardioverter-Defibrillator Active Can Investigators, / Bardy, G.H. / Yee, R. / Jung, W., *Journal of the American College of Cardiology*, Aug 1996

Objectives. The purpose of this study was to prospectively examine in a multicenter study the methods of use, efficacy and complications of a unipolar cardioverter-defibrillator in patients at risk for sudden cardiac death. Background....

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G Id, M.R. / Peters, R.W. / J hns n, J.W. / Shor fsky, S.R., *Journal of the American College of Cardiology*, Nov 1996

Objectives. The aim of this study was to compare complications in a large cohort of patients undergoing pectoral cardioverter-defibrillator implantation with a subcutaneous or submuscular approach. Background. Pectoral placement of...

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Gold, M.R. / Peters, R.W. / Johnson, J.W. / Shorofsky, S.R., *Journal of the American College of Cardiology*, Nov 1996

Objectives. The aim of this study was to compare complications in a large cohort of patients undergoing pectoral cardioverter-defibrillator implantation with a subcutaneous or submuscular approach. Background. Pectoral placement of...

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Molina, J.E., *The Annals of Thoracic Surgery*, Feb 1997

Background. Infection of implantable defibrillators or pacemakers is a serious complication, reported with increasing frequency probably because of an increase in the total number of devices implanted due to a change in trends in the...

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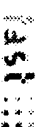
J F Obadia / G Kirkorian / G Rescigno / M el Farra / J F Chassignolle / P Touboul, *Pacing Clin Electrophysiol*, Jun 1996

...system for automatic implantable cardioverter defibrillators (ICDs) has been one...may be required and implanted either in a subcutaneous...generator was then implanted through the left subcostal incision in a subdiaphragmatic...

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- ☐ 11. Treatment of malignant ventricular arrhythmias with the automatic implantable cardioverter defibrillator.

A D Slater / I Singer / C S Stavens / C Zee-Cheng / B L Ganzel / J Kupersmith / C Mavroudis / L A Gray, *Ann Surg*, May 1989

...treated with the automatic implantable cardioverter-defibrillator (AICD) in a 14-month period...patients considered for AICD implant failed a mean of 3.6 antiarrhythmic...patients and a mediansternotomy incision in 11 patients in conjunction...

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Complications Associated With Pectoral Cardioverter-Defibrillator Implantation: Comparison of Subcutaneous and Submuscular Approaches

Michael R. Gold, Robert W. Peters, James W. Johnson and Stephen R. Shorofsky

Received 27 March 1996; revised 12 June 1996; accepted 26 June 1996. Available online 31 August 1998.

Abstract

Objectives. The aim of this study was to compare complications in a large cohort of patients undergoing pectoral cardioverter-defibrillator implantation with a subcutaneous or submuscular approach.

Background. Pectoral placement of implantable cardioverter-defibrillator (ICD) pulse generators is now routine because of downsizing of these devices. Subcutaneous implantation has been advocated by some because it is a simple surgical procedure comparable to pacemaker insertion. Others have favored submuscular insertion to avoid wound complications. These surgical approaches have not been compared previously.

Methods. The subjects for this study were 1,000 consecutive patients receiving a Medtronic Jewel ICD at 93 centers worldwide. Cumulative follow-up for all patients was 633.7 patient-years, with 64.9% of patients followed up for ≥ 6 months. The complications evaluated were erosion, pocket hematoma, seroma, wound infection, dehiscence, device migration, lead fracture and dislodgment.

Results. Subcutaneous implantation was performed in 604 patients and submuscular implantation in the remaining 396. The median procedural times were shorter for subcutaneous implantation ($p = 0.014$). In addition, the cumulative percentage of patients free from erosion was greater for subcutaneous implantations ($p = 0.03$, 100% vs. 99.1% at 6 months). However, lead dislodgment was more common with subcutaneous implantations ($p = 0.019$, 2.3% vs. 0.5% at 6 months) and occurred primarily during the first month postoperatively. Overall, there were no significant differences in cumulative freedom from complications between groups (4.1% vs. 2.5%, $p = 0.1836$).

Conclusions. Subcutaneous pectoral implantation of this ICD can be performed safely and has a low complication rate. This approach requires a simple surgical procedure and, compared with the submuscular approach, is associated with shorter procedure times and comparable overall complication rates. However, early follow-up is important in view of the increased lead dislodgment rate.

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